

Remarks

According to the Office Action mailed on April 29, 2004 (the "Office Action"), Claims 1-20 are pending in the application. Claims 1-20 have been rejected under 35 U.S.C. § 103(a). More particularly, claims 1-3 and 5-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over "Recent Progress in the Development of a Clinically Useful Microencapsulated Olfactory Function Test" by Doty et al. (the "RPDOT") in view of WO 89/00398 of Cotman ("Cotman") and U.S. Patent No. 3,570,139 of Ladd, et al. ("Ladd '139"). Claims 1-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the RPDOT in view of Cotman and U.S. Patent No. 2,977,689 of Rugland et al ("Rugland '689"). Claims 14-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the RPDOT in view of Cotman, Ladd '139 and Buschke 5,230,629 ("Buschke '629").

I. CLAIMS 1-3 AND 5-13 ARE NOT OBVIOUS IN VIEW OF THE RPDOT, COTMAN AND LADD '139.

According to the Office Action, claims 1-3 and 5-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the RPDOT in view of Cotman and Ladd '139. More particularly, the Office Action states that the RPDOT discloses an olfactory test for self-administered screening of neurological disease containing most of the elements of the claims including, a plurality of odor-containing sources as required by claim 1, each odor-containing source containing a familiar odor as required by claim 1, a plurality of labels located adjacent to each of the odor-containing sources and providing choices of possible identity of the odor-containing source as required by claim 1. The Office Action further states that four labels are provided each odor-containing source, as required by claim 5. Still further, the Office Action states that the RPDOT describes a plurality of labels for each odor-containing source being distinctly different from

each other as required by claim 6. The Office Action goes on to state that the RPDOT describes a plurality of odor-containing sources being distinctly different from each other, as required by claim 7.

Applicant respectfully submits that the RPDOT does not disclose an olfactory test for self-administered screening of neurological disease. Instead, the RPDOT discloses only a self-administered mass screening procedure for diagnosing smell dysfunctions. The RPDOT does not correlate the diagnosis of smell dysfunctions with neurological diseases such as Alzheimer's. In fact, the RPDOT appears to focus its analysis on the differences in olfactory functions as between males and females. Indeed, the RPDOT appears to be directed to determining that women perform better than men on the olfactory test described therein. However, the RPDOT does not disclose an olfactory test for self-administered screening of neurological diseases such as Alzheimer's.

Referring again to the Office Action, it acknowledges that the RPDOT lacks an explicit teaching of a removably covered answer key as required by claim 1, a first, second and third instruction for self-administering, self-scoring and self-interpreting the olfactory test as required by claim 1, an odor-containing source having a unique distinguishing feature as required by claim 10, a neurological disease being Alzheimer's as required by claim 11, and a first sheet with an instruction for a medical professional as required by claim 12. According to the Office Action, however, Ladd '139 discloses a booklet having an olfactory test thereon which teaches incorporating a removably covered answer key where it is considered that since the display page would be covered by a variety of other pages while the user looks at the question page then the

display page is removably covered. The Office Action further states that Cotman discloses a kit for olfactory testing which teaches providing instructions for self-scoring the olfactory test in order to diagnose a possible onset of Alzheimer's disease as required by claim 11. The Office Action also states that Cotman further teaches an odor-containing source having a unique distinguishing feature.

Based upon the foregoing, the Office Action concludes that it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to provide a removably covered answer key and instructions with the test of the RPDOT for the purpose of positive identification and interpretation of the results of the test, especially since the booklet of the RPDOT is concerned with self-administration of the olfactory test. The Office Action further states that it would have been obvious to provide a unique distinguishing feature on the odor source for the purpose of clear identification of the location of the source.

Applicants agree with the Office Action to the extent that it states the RPDOT does not teach or suggest an olfactory test comprising a removably covered answer key as required by claim 1, a first, second and third instruction for self-administering, self-scoring and self-interpreting the olfactory test as required by claim 1, or an odor-containing source having a unique distinguishing feature as required by claim 10. Further, Applicants agree with the Office Action to the extent that it acknowledges the RPDOT does not teach or suggest an olfactory test adapted to correlate smell dysfunction with a neurological disease such Alzheimer's as required by claim 11 or a first sheet with an instruction about the olfactory test for a medical professional as required by claim 12.

Applicants further submit that Ladd '139 does not describe an olfactory test for self-screening neurological diseases such as Alzheimer's. Further, Ladd '139 does not describe an olfactory test comprising questions and answers as contemplated by the claimed invention. Instead, Ladd '139 describes and claims a teaching apparatus directed to establishing an association between a selected chemical sense stimulus and an identification thereof. More particularly, stimulus page 30 of the teaching apparatus described and claimed by Ladd '139 does not include any questions to be answered by the user. Instead, stimulus page 30 includes stimulus producer 10 in the form of separable portions 44 which are adapted to be removed from stimulus sheet 30 and placed on display page 28. There is no teaching or suggestion in Ladd '139 that stimulus sheet 30 includes any questions to be answered by the user as required by the claimed invention. In addition, display page 28 of the teaching apparatus described and claimed by Ladd '139 is not an answer key that is adapted to be scored for correct and incorrect answers. Instead, display sheet 28 includes display section 44 which comprises a legend such as "You can smell the peppermint canes too", or "Scratch the peppermint cane and sniff", or "This is the smell of peppermint." However, display sheet 28 is not an answer key adapted to be scored for correct and incorrect answers as contemplated by the claimed invention.

Thus, Ladd '139 does not disclose a booklet having an olfactory test thereon which incorporates a removably covered answer key and a question page. Further, Ladd '139 does not teach or suggest an olfactory test for self-screening neurological diseases as defined by the claimed invention.

Still further, Applicants respectfully submit that Cotman does not disclose an olfactory test for self-screening neurological diseases without the assistance of a medical professional. Indeed, Cotman describes and claims a diagnostic test for Alzheimer's disease which requires assistance from a medical professional. More particularly, Cotman discloses a kit containing "instructions setting forth the protocols and the manner of interpreting the results according to the method of the invention described above." Cotman, however, does not disclose instructions for self-administering the test without the assistance of a medical professional or instructions for self-scoring the test using an answer key to determine an olfactory test result without assistance from a medical professional. In fact, Cotman expressly states that the test described and claimed therein is conducted by an "administrator" who administers the test to "the subject" who is "presented with a sample odor and then immediately asked to identify which of three successively presented test odors it matches." Cotman further states that "[i]f desired, the materials can be supplied as individual bubbles on a test card so the **administrator** of the test can break the bubbles in the correct order from an individual card for each **subject**." (emphasis added). In addition, Cotman describes the use of the claimed invention on animals. The use of the test described by Cotman on animals is further evidence that the test is not adapted to be self-administered, self-scored or self-interpreted without assistance from a medical professional.

Thus, Cotman does not teach or suggest an olfactory test for self-screening neurological diseases without assistance from a medical professional. While Cotman discloses a kit for olfactory testing which teaches providing "instructions setting forth the protocols and the manner of interpreting the results according to the method of the invention," it does not teach or suggest an olfactory test that provides instructions for the self-administration, self-scoring or self-

interpretation without assistance from a medical professional as required by the claimed invention. Simply put, the olfactory test of Cotman requires a medical professional for administration, scoring and interpretation of the test, and the claimed invention does not.

In addition, the diagnostic test of Cotman requires that the odor-containing sources used to diagnose Alzheimer's disease consist of odors which are not ordinarily experienced by the user. More particularly, Cotman expressly states that the test "specifically does not employ such familiar odors as mint, wintergreen, vanilla, cinnamon, and so forth that would be part of the subjects (sic) previous experience." Further, Cotman does not teach or suggest a booklet including a plurality of pages each of which has a plurality of labels and a removably covered answer key.

Referring again to the Office Action, it states that "[r]egarding the specifics of the first, second and third instructions as required by claims 1, 2, 3 and 12, it would have been obvious to provide a first, second and a third instruction with the specifics of claims 1, 2, 3 and 12 since it would only depend on the intended use of the assembly and the desired information to be displayed." The Office Action then cites the decision of *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983), stating that it has been held when the claimed printed matter is not functionally related to the substrate, it will not distinguish the invention from the prior art in terms of patentability. The Office Action then states the fact that the content of the printed matter placed on the substrate may render the device more convenient by providing an individual with a specific type of instruction does not alter the functional relationship. The Office Action continues stating that mere support by the substrate for the printed matter is not the kind of functional relationship

necessary for patentability. Thus, the Office Action concludes, there is no novel and unobvious functional relationship between the printed matter (e.g., instructions) and the substrate (e.g., olfactory test) which is required for patentability.

Applicants submit that while the *In re Gulack* decision states "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability," the printed matter of the first, second and third instructions of the claimed invention is functionally related to the substrate. More particularly, the printed matter of the first, second and third instructions of the claimed invention is functionally related to the substrate, and it is both novel and non-obvious. The printed matter of the first, second and third instructions not only renders the claimed invention more convenient by providing a user with a specific type of instruction as indicated by the Office Action, the printed matter enables the user to self-administer, self-score and self-interpret the results of the olfactory test without assistance from a medical professional. Without the printed matter of the first, second and third instructions, the claimed invention would not be functional without assistance from a medical professional. As a result, the printed matter does more than just render the claimed invention more convenient to the user, and the functional relationship between the printed matter and the substrate is more than the substrate merely supporting the printed matter.

Further, the functional relationship between the printed matter (the instructions) and the substrate (the olfactory test) is both novel and non-obvious. None of the references cited in the Office Action teach or suggest an olfactory test for self-screening neurological diseases which may be self-administered, self-scored and self-interpreted without assistance from a medical

professional. Consequently, the printed matter of the first, second and third instructions is functionally related to the substrate, novel and non-obvious.

Referring again to the Office Action, it states that regarding the specific layout as required by claims 8 and 9, the Examiner takes "official notice that such an arrangement of labels and odor-containing sources is utilized in the UPSIT described in the RPDOT reference."

Applicants respectfully submit that the RPDOT does not disclose the arrangement of labels and odor-containing sources described and claimed by claims 8 and 9 of the Applicants' application. Indeed, the RPDOT discloses only the following odor-containing sources: (1) lilac; (2) chili; (3) coconut; (4) whiskey; (5) chocolate extract; and (6) menthol. By contrast, claim 9 of the Applicants' application recites the following odor-containing sources which are not identified by the RPDOT: (1) cinnamon; (2) turpentine; (3) lemon; (4) smoke; (5) rose; (6) paint thinner; (7) banana; (8) pineapple; (9) gasoline; (10) soap; and (11) onion. Further, the RPDOT does not teach or suggest any specific labels other than the names of the six odor-containing sources identified above. By contrast, claim 8 of the Applicants' application recites a plurality of labels which are not identified by the RPDOT including the following: (1) fruit; (2) woody; (3) dog; (4) black pepper; (5) motor oil; (6) garlic; (7) apple; (8) grass; (9) grape; (10) strawberry; (11) mint; (12) lime; (13) watermelon; (14) peanut; (15) cherry; and (16) gasoline. Of course, claim 8 also recites the eleven odor-containing sources which are not identified in the RPDOT. As a result, the Applicants' claimed invention recites no less than twenty-seven (27) odor-containing sources and labels that are not taught or suggested by the RPDOT. Consequently, the specific

layout required by claims 8 and 9 of the Applicants' application is not taught or suggested by the RPDOT.

Finally, Applicants respectfully submit that the statement made in the Office Action's explanation of the rejections of claims 14-20 is applicable to the rejections of claims 1-3 and 5-13. More particularly, Applicants agree with the Office Action's acknowledgment that the "RPDOT, as modified by Cotman and Ladd '139" does not disclose "the steps of self-administering, self-scoring and self-interpreting the test without assistance from a medical professional." The absence of any teaching or suggestion to provide a self-administering, self-scoring and self-interpreting olfactory test for diagnosing neurological diseases without professional medical assistance in the combined disclosures of the RPDOT, Cotman and Ladd '139 dictates that the rejections under 35 U.S.C. § 103(a) of claims 1-3 and 5-13 should be withdrawn.

Accordingly, Applicants respectfully submit that claims 1-3 and 5-13 are not obvious in view of the RPDOT, Ladd '139 and/or Cotman.

II. CLAIMS 1-13 ARE NOT OBVIOUS IN VIEW OF THE RPDOT, COTMAN AND RUGLAND '689.

According to the Office Action, claims 1-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the RPDOT in view of Cotman and Rugland '689. More particularly, the Office Action states that "[a]lthough the RPDOT and Cotman disclose most of the elements, as stated above, the references fail to teach a removably covered answer key (as required by claim 1) utilizing a sealed cover sheet (as required by claim 4)." The Office Action states,

however, Rugland '689 discloses a multiple choice test which teaches that it is known to provide a removably covered answer key utilizing a sealed cover sheet. The Office Action concludes, therefore, it would have been obvious to incorporate a removably covered answer key utilizing a sealed cover sheet in the device of the RPDOT, as modified by Cotman, for the purpose of preventing the examinee from gaining access to the scoring sheet as the RPDOT is directed to a self-administered test.

Applicants respectfully submit that neither the RPDOT nor Cotman teaches or suggests the claimed invention for the reasons described above in Section I. Further, while Rugland '689 discloses a multiple choice response device, there is no teaching or suggestion to combine the multiple choice response device with the RPDOT and/or Cotman. Still further, even if the teachings of Rugland '689 are combined with the teachings of the RPDOT and/or Cotman, the differences between the claimed invention as a whole and the combined teachings of the RPDOT, Cotman and Rugland '689 would not have been obvious at the time of the invention to one having ordinary skill in the art.

More particularly, the combined teachings of the RPDOT, Cotman and Rugland '689 do not disclose the method or apparatus of the olfactory test of the claimed invention. Like the RPDOT and Cotman, Rugland '689 does not teach or suggest an olfactory test for self-screening neurological diseases which may be self-administered, self-scored and self-interpreted without assistance from a medical professional. In fact, Rugland '689 does not even teach or suggest an olfactory test. Further, Rugland '689 does not teach or suggest a booklet comprising a plurality of pages, each of which contains a plurality of odor-containing sources, or instructions for self-

interpreting the results indicated by the device. Consequently, the combination of the RPDOT, Cotman and/or Rugland '689 does not teach or suggest the olfactory test for self-screening neurological diseases as defined by claims 1-13.

Accordingly, claims 1-13 are not obvious in view of the RPDOT, Cotman and/or Rugland '689.

III. CLAIMS 14-20 ARE NOT OBVIOUS IN VIEW OF THE RPDOT, COTMAN, LADD '139 AND BUSCHKE '629.

According to the Office Action, claims 14-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the RPDOT in view of Cotman, Ladd '139 and Buschke '629. More particularly, the Office Action states the RPDOT, as modified by Cotman and Ladd '139, discloses most of the elements of the claims, as stated above, but for the steps of self-administering, self-scoring and self-interpreting the test without assistance from a medical professional as required by claim 14. The Office Action states, however, that Buschke '629 discloses a medical test device for the determination of Alzheimer's which teaches that it is known to provide an at-home self-test which allows for self-administration, self-scoring and self-interpreting the results of the test without the help of a medical professional. The Office Action concludes, therefore, it would have been obvious to incorporate the steps of self-administering, self-scoring and self-interpreting with the test of the RPDOT without the assistance from a medical professional for the purpose of providing a reliable, rapid test for self-testing at home or elsewhere, especially since the RPDOT clearly teaches that its test is self-administered.

As described above, neither the RPDOT, Cotman nor Ladd '139 teaches or suggests the claimed invention. Further, Buschke '629 discloses a device and method for measuring and reporting the

user's cognitive speed. More particularly, the device described and claimed by Buschke '629 utilizes stimuli in the form of randomly-generated digits, i.e., numbers. The device then requests the user to perform a cognitive function such as copying the digit or subtracting a number from the digit. The user then performs the cognitive function. Thereafter, the device compares the user's answers against the correct answers and measures the user's cognitive speed. Finally, the device reports the correct answers and the user's cognitive speed.

Buschke '629, however, does not teach or suggest an olfactory test for self-screening neurological diseases such as Alzheimer's. In fact, Buschke '629 does not disclose any form of test for self-screening neurological diseases. Still further, Buschke '629 does not teach or suggest an olfactory test that may be self-interpreted without the assistance of a medical professional. While Buschke '629 describes a device that automatically reports a score, e.g. the user's cognitive speed, the device does not interpret that score for the user. Buschke '629 contains no written description of the manner in which the measured results of the cognitive speed test are interpreted for the user and no written description of the substance of any such interpretation provided by the device to the user. In addition, Buschke '629 does not disclose a booklet comprising a plurality of pages, each of which includes a plurality of odor-containing sources, or a removably covered answer key.

Accordingly, Applicants respectfully submit that claims 14-20 are not obvious in view of the RPDOT, Cotman, Ladd '139 and/or Buschke '629.

IV. CONCLUSION

For all of the foregoing reasons, Applicants respectfully submit that the rejections of their claims cited in the Office Action mailed on April 29, 2004 should be withdrawn, and claims 1-20 should be allowed.

Respectfully submitted,



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